REMARKS

Applicants respectfully request entry of the Amendment and reconsideration of the claims.

Claims 3, 19 and 20 have been amended. Claims 19 and 20 have been amended to correct obvious typographical errors. Claim 3 has been amended to clarify the claim. New claims 21-23 have been added. Support can be found throughout the specification, including at page 40, line 14 to page 41, line 11 and at page 69, line 25 to page 70, line 25. No new matter has been added through the amendments or new claims.

Claims 1-3, 5-11, and 14-23 will be pending upon entry of this amendment.

Applicants believe this Amendment and Response is being timely filed as the 3 month due date was May 28, 2005, which fell on a Saturday. This Amendment was filed on the next business day, which is May 31, 2005, after the Memorial Day holiday. Accordingly Applicants have not filed an extension of time or paid the extension fee.

Provisional Double Patenting Rejections

The Examiner provisionally rejects claims 1-3, 5-11 and 14 for obvious-type double patenting as allegedly unpatentable over claims 1-5, 13-15, and 20-22 of copending Application No. 08/943,771. The Examiner also provisionally rejects claims 19 and 20 for statutory double patenting under 35 U.S.C. §101 as claiming the same invention as claims 1 and 5 of copending Application No. 08/943,771. Applicants advise the Examiner that copending Application No. 08/943,771 will be abandoned. Applicants respectfully request that the Examiner withdraw this rejection upon abandonment of copending Application No. 08/943,771.

Rejections under 35 U.S.C. §112, first paragraph

A. Rejection under Written Description

The Examiner rejects claims 1-3, 5-11, and 14-20 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, the Examiner alleges that the specification does not provide support for the term "progeny thereof". Applicants respectfully traverse.

As noted in the Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112, ¶1, "Written Description" Requirement ("the guidelines"), there is a "strong presumption" that an adequate written description of the claimed invention is present when the application is filed. 66(4) *Fed Reg.* 1099, 1105 (2001); *see also, In re Wertheim,* 191 USPQ 90, 97 (CCPA 1976). The guidelines further state that "[T]he examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." 66(4) *Fed. Reg.* at 1107; 191 USPQ at 97. Compliance with the written description requirement does not require an applicant to describe exactly the subject matter claimed; rather, the description must clearly allow a person of ordinary skill in the art to recognize that he or she invented what is claimed. *Vas-Cath Inc. v. Mahurkar,* 19 USPQ2d 1111, 1116 (Fed. Cir. 1991).

The instant specification supports the term "progeny thereof" so a person of ordinary skill in the art would recognize that Applicants had possession of the claimed subject matter. Applicants disclose the use of "the hybridoma method" as first described by Kohler and Milstein in *Nature* (1975, 256: 495-497). *See* specification at page 10, lines 3-6. Applicants submit Appendix I, section A-12 of Janeway's *Immunobiology* (5th ed.), which describes Kohler and Milstein's hybridoma method. As described in Appendix I, section A-12 and graphically depicted in Figure A.14, hybridomas can be grown in culture and a hybridoma producing a monoclonal antibody can be cloned. One of skill in the art would understand that in order to obtain antibodies from the deposited hybridoma, the hybridoma is cultured and as such progeny of the hybridoma are generated. The examiner has presented no evidence that such progeny would be changed. Moreover, the Examiner indicated that the use of this term was new matter. Applicants submit that the term was present in the claims as originally filed and as such does not constitute new matter. As such, Applicants respectfully request removal of the rejection under 35 U.S.C. §112, first paragraph.

B. Rejection under Enablement

The Examiner also rejects claim 3 under 35 U.S.C. §112, first paragraph, for allegedly not providing enablement for a variable region of the antibody of claim 1 or 2. Applicants have amended claim 3 to recite "an antigen binding fragment". Support can be found throughout the

specification, including at page 8, lines 18-20. The Examiner asserts that a complete heavy and light chain variable region, each including 3 CDRs, are required for binding an antigen. Applicants respectfully traverse.

To meet the enablement requirement of 35 U.S.C. §112, first paragraph, a specification must contain a sufficient description to enable one skilled in the art to make and use the claimed invention. *See, e.g., Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004); MPEP §2164.01. The specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without "undue experimentation." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1334, *citing, Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) and *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991).

The Examiner contends that all six CDRs are required for antigen binding. Applicants respectfully disagree. In the first instance, the Janeway textbook discusses the antigen binding site for an antibody with both V_H and V_L domains. In an antibody having both V_H and V_L domains, the 6 CDRs can contribute to antigen binding specificity. However, the Janeway textbook does not state that 6 CDRs are required for binding an antigen. In fact, the Janeway textbook, or at least the section of the textbook cited, does not address the minimum fragment necessary for antigen binding.

Secondly, Applicants provide two representative articles demonstrating that molecules containing a single variable domain can bind to antigen. In the Cai et al. reference, the authors show that a variable heavy chain domain can bind with high affinity to a melanoma antigen. The Desmyter et al. reference describes naturally occurring antibodies that only have a heavy chain variable domain. Thus, Applicants submit that one of skill in the art would understand that not all six CDRs are required for antigen binding.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

Request for an Interview

Applicants request an interview with the Examiner to resolve any remaining issues. The Examiner is requested to contact Applicants' representative upon receipt of these papers.

SUMMARY

In view of the foregoing, the Applicants believe that all claims as currently pending are in condition for allowance and such action is respectfully requested. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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